



# Biotech Daily

Monday November 17, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECHS DOWN: PHYLOGICA UP 56%, LABTECH DOWN 23%**
- \* **BIOTA LANI PHASE III TRIALS READY FOR ENROLMENT**
- \* **MEDICAL THERAPIES OFFERS SHARE PLAN AT 4¢ A SHARE**
- \* **CYTOPIA DOSES 1<sup>st</sup> PHASE Ib/II BRAIN CANCER PATIENT**
- \* **PROGEN SPIN-OUT PHARMASYNTH FOR SALE**
- \* **DR MERVYN JACOBSON INCREASES IN GENETIC TECHNOLOGIES**
- \* **FMR, FIDELITY REDUCES TO 9.7% IN CSL**

## MARKET REPORT

The Australian stock market fell a further 2.3 percent on Monday November 17, 2008 with the All Ordinaries down 86.5 points to 3,639.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and seven were untraded.

Phylogica was best, up 2.5 cents or 55.56 percent to seven cents with 100,000 shares traded, followed by Cellestis up 30 cents or 14.29 percent to \$2.40 and Prana up four cents or 11.11 percent to 40 cents.

Living Cell climbed 9.09 percent; Biota was up 7.5 percent; Pharmaxis rose 4.78 percent; with Optiscan and Progen up more than one percent and Universal Biosensors up less than one percent.

Labtech led the falls, down 3.5 cents or 22.58 percent to 12 cents with 90,000 shares traded, followed by Proteome down 16.67 percent to five cents, Peplin down 14.67 percent to 32 cents, Heartware down 14.29 percent to 48 cents and Avexa down 11.11 percent to 12 cents.

Arana lost 8.54 percent; Clinuvel fell 7.84 percent; Genetic Technologies and Phosphagenics were down more than six percent; Alchemia, Circadian and Novogen lost more than five percent; Sirtex fell 4.33 percent; CSL and Resmed were down more than three percent; with Polartechnics and Ventracor down more than two percent.

## [BIOTA](#)

Biota says the multi-centre phase III clinical trial of its long acting neuraminidase inhibitor CS-8958 is ready to begin patient treatment.

Biota said patients were expected to enrol into the study progressively throughout the Asian influenza season.

The company said the phase III multi centre study would be conducted in Japan, Taiwan, Hong Kong and Korea involving adult patients who have confirmed, naturally acquired influenza A or B.

A double blinded phase II trial in Japan concluded that inhaled CS-8958 administered once only was statistically indistinguishable from 75mg of oseltamivir (Tamiflu) administered twice daily for five consecutive days (see Biotech Daily; July 31, 2008).

Biota chief executive officer Peter Cook told Biotech Daily that a second arm of the phase II trial conducted in Taiwan remained open and would continue in parallel with the pivotal phase III trial.

Biota said in its media release the trial would use time to symptom resolution as its primary end point, after a single inhaled dose of CS-8958.

The double blind, non-inferiority study uses 75 mg of oseltamivir, twice daily for five days as its control.

Safety will be also assessed in the study.

A second phase II/III paediatric study will also be conducted in Japan on children less than nine years of age.

Biota said the paediatric study would use the same primary end point as the adult study, but using a control of 2 mg/kg of oseltamivir, twice a day for five days.

Biota said CS-8958 was a long acting neuraminidase inhibitor, discovered by Daiichi Sankyo and co-owned with Biota.

A total of \$US5.6 million of Western clinical programs for CS-8958 have been or are intended to be funded by the US National Institute of Health.

Biota said the drug's profile suggests that a single inhaled dose of CS-8958 should be efficacious for the treatment of influenza and an inhaled dose once a week, to maintain prophylaxis.

Pre-clinical tests have shown CS 8958 to be effective against influenza A & B virus as well as against the H5N1 avian influenza virus.

Mr Cook said that a Western phase I trial would be conducted and the results of that trial and the Japanese multi-centred phase III trial would be the basis of an investigational new drug application to the US Food and Drug Administration.

He said the Japan-based pivotal phase III trial could extend over two influenza seasons, depending on enrolments.

Biota climbed three cents or 7.5 percent to 43 cents.

## [MEDICAL THERAPIES](#)

Medical Therapies is offering eligible shareholders up to \$5,000 worth of shares at four cents a share.

Medical Therapies said the funds raised would be used to continue the development and commercialization of the Midkine intellectual property portfolio.

The company said the plan was limited to 37,438,607 shares.

Medical Therapies said the record date was November 14, 2008, the offer opens on November 19 and closes on December 5.

Parcels of shares can be bought in a range from \$2,000 to \$5,000.

Medical Therapies was untraded at five cents.

## CYTOPIA

Cytopia has begun dosing patients in its phase Ib/II study of CYT997, to treat glioblastoma multiforme, an aggressive brain cancer.

Cytopia says the glioblastoma multiforme clinical trial is the company's first phase II efficacy study in highly vascular, solid tumor indications and the first time the company's novel vascular-disrupting anticancer agent, CYT997 is being investigated in a tumor of the central nervous system.

Cytopia said glioblastoma multiforme was treated by surgical resection, and/or radiation and chemotherapy.

Despite these treatments, the condition recurs in most patients resulting in significantly limited life expectancy, the company said.

Cytopia said glioblastoma multiforme tumors were highly vascular, rendering them potentially susceptible to destruction by an anti-vascular agent such as CYT997.

The clinical study will investigate the activity of CYT997 in combination with two other marketed anticancer agents in about 30 patients.

The director of oncology at Melbourne's Frankston Hospital, Dr Jason Lickliter, is the program's study chairman.

Cytopia said it was "well advanced" to opening its second clinical site for the study at a cancer centre in Sydney with enrolment expected "within weeks".

The company said it intended to file the requisite submissions to enable dosing at two additional sites in Australia to begin early in 2009, with US and European clinical sites also being assessed for the later stages of the study.

Cytopia said the trial followed the conclusion of the company's phase I safety study for intravenous CYT997, in which a prolonged delay in tumor growth was observed in seven of the study's 31 advanced cancer patients (see Biotech Daily; November 13, 2007).

Cytopia was untraded at 15 cents.

## PROGEN PHARMACEUTICALS

Progen says its wholly-owned biopharmaceutical manufacturing business, Pharmasynth Pty Ltd, is for sale.

Progen spun-out its biopharmaceutical manufacturing division into Pharmasynth in July 2008 (see Biotech Daily; July 2, 2008).

Progen said the decision to spin-out and sell Pharmasynth was made so Progen could focus on drug development.

Progen said it was expected that it would engage any acquirer of the business to assist in the technology transfer of PI-88 raw materials manufacturing to any licensee.

The company said Pharmasynth had been successful in winning additional external manufacturing contracts and is currently profitable.

The Pharmasynth team, led by chief executive officer Les Tillack, has more than 15 years of contract manufacturing experience in the development and manufacture of biopharmaceutical material for phase I to phase III clinical trials and the production of veterinary products for commercial sale.

Progen said the London-based chartered accountants and business advisers PKF Transaction Services had been engaged to manage the sale process.

An information memorandum is available from PKF Australia and expressions of interest need to be submitted to PKF by December 19, 2008.

Progen was up one cent or 1.59 percent to 64 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies founder Dr Mervyn Jacobson has increased his holding in the company ahead of its controversial meeting on November 19, 2008.

Dr Jacobson has held about 40 percent of the company and in a notice to the ASX today said he had increased his holding by 580,826 shares bought directly and indirectly on market for \$34,849.56.

Earlier this month, Dr Jacobson directly and indirectly bought 119,174 shares on-market. Dr Jacobson holds 98,000,000 shares through JGT ApS, 49,000,000 shares through Mervyn Jacobson ApS and 4,631,900 shares directly in his own name. The total holding gives Dr Jacobson 40.47 percent of the total share issue.

It has been previously reported that investors holding about eight percent of the company have given an address owned by Dr Jacobson as their mailing address.

Dr Jacobson has proposed a resolution to replace the majority of the board (see Biotech Daily; September 18, 19, 22 and October 22, 2008).

Initially he proposed Grahame Leonard to replace chairman Henry Bosch, managing director and chief executive officer Michael Ohanessian as well as directors John Dawkins, David Carruthers and Monash University deputy chancellor Dr Leanne Rowe. Company co-founder Fred Bart is standing for reelection but is not opposed by Dr Jacobson.

Following Mr Leonard withdrawing from the election, Genetic Technologies said Aeris Environmental chief executive officer Huw Jones had been proposed to be appointed by Dr Jacobson and Mr Bart should the spill resolution be successful.

The annual general meeting will be held at 10am on Wednesday.

Genetic Technologies fell 0.4 cents or 6.67 percent to 5.6 cents.

## CSL

The US-based FMR Corp and Fidelity Investments reduced their substantial shareholding in CSL from 66,200,304 shares (10.47%) to 58,346,595 shares (9.68%) between August 22, 2008 and November 13, 2008.

Shares were sold in small to very small parcels at prices ranging from \$US20.76 to \$US35.01 a share.

CSL fell \$1.28 or 3.37 percent to \$36.70.